Petition

Reply to Office Action, This action is non-final

Applicant: Shin-Jen Shaio

Application No.: 10/554,315

Filed Date: 10-24-2005 Group Art Unit: 1614

Attorney Docket No.: Examiner: THOMAS, TIMOTHY P

Confirmation No.: 2698

To the Commissioner of Patents:

The applicant was notified by The Examiner about Office communication mailed on 09/15/2011, and the period for reply is set to expire 1 month from the mailing date of this communication. In which claims 64-66, 68-74, 77, 78 and 81-93 are subject to restriction and/or election requirement.

The applicant had filed on 08 August 2011 a petition replied to communication in which:

1. Again argue about "A general principle of the invention"

1). The applicant did no mean that request the Examiner to examine using the rule of paragraph 145 of Second use medical guidelines of UK, but wish the Examiner to understand the generic relationship of this invention. A traditional new drug invention which grants usually by its generic chemical structure would be a good example to induce present invention to meet the same requirements shown as following term.

2). In the examination of a new drug invention having a function group is -COOH, there was usually a structure of designed compound that presented in a general form of the said new drug, saying $R_1R_2R_3CCOOH$. The variable structure groups of R_1, R_2 and R_3 may change in a very wide range of category. It shows only the aim active functional group of –COOH for the ailment treatment that the compound would easily being granted for patent. In fact, there are very widely range of compounds existed and show any form and would be approved by the Examiner and granted. So, as the same manner, would please the Examiner taking the same standard of examination for this invention has the general principle of relationship of edible acids all having the same active function group is –COOH. The common action of that active function group "–COOH" is to release the same proton to lower the humoral pH value and treating diseases in this invention. In which phosphoric acid did the same role of releasing proton to lower humoral pH value and treating diseases.

2. Also again argue about "The prior art Ohashi, et al. (US 6,297,244B1)" that is nothing to do with this invention at all. The evidences are:

1). The referred prior art as its abstract says: A stabilized pharmaceutical composition comprising (R)-2-(4-bromo-2-fluorobenzyl)-1,2,3,4-tetrahydropyrrolo[1,2-a]pyrazine-4-spiro-3'-pyrrolidine-1,2',3,5'-tetrone (hereinafter, referred to as "AS-3201") and as a stabilizer at least one acidic substance having an acidity more potent than that of AS-3201, such as ascorbic acid, citric acid, tartaric acid, lactic acid, maleic acid, malic acid or phosphoric acid. Therefore, even though they contain some of acids, they are used as a stabilizing agent for "AS-3201", and do not concern any treatment of ailment at all. The claims of present invention claim to lower humoral pH and treat ailments.

2). In the term of "Field of the Invention" of said prior art it said "The present invention relates to a stabilized pharmaceutical composition of (R)-2-(4-bromo-2-fluorobenzyl)-1,2,3,4-tetrahydropyrrolo[1,2-a]pyrazine-4-spiro-3'-pyrrolidine-1,2',3,5'-tetrone (hereinafter, referred to as "AS-3201") having a potent aldose reductase inhibitory activity.

3). Through all document of Ohashi et al. (US 6,297.244 B1), there is no any description about the disease treatment concerning present invention.

4). It is obviously that the said prior art is using acids as a stabilizer for the compound of "AS-3201" and without any others purpose. On top of that, the compound of "AS-3201" is having a potent aldose reductase inhibitory activity which does not link any purpose of the disease treatment of present invention.

5). For the purpose of stabilizing "AS-3201" said acid is used as a stabilizer, so that the said acid is always accompanied with "AS-3201" and never exits alone. In other words, the structure of said prior art is neither "AS-3201" nor "stabilize (acid)" individually alone, but a mixed compound of "AS-3201 and stabilizer (acid) they are always binding together" and having a potent aldose reductase inhibitory activity. In which the range of acid never be used alone in that art. In that manner, can we deem that the present invention is told by Ohashi et al. (US 6,297.244 B1)? And the structure of said prior art is like present invention, and do the same results? It is never. Therefore the Examiner's determination is not fair and injustice.

3. The applicant select number (3) "A product, a process specially adapted for the manufacture of the said product, and a use of the said product" for multiple categories of invention which the Examiner constructed. The applicant cancels all edible carboxylic acids and claims phosphoric acid independently. The use of phosphoric acid in ailment is allergy which concerns histamine relatively.

4. The general principle of the invention is supplying protons in body fluid by administering edible acid. Protons are generic factors, which released from carboxyl function group, phosphoric acid or gluconolactone, and lowering the humoral pH, which causes the treatment of ailments finally. This general principle of the invention is fully supported by the description of present application. This general principle was demonstrated in testing the rate of inhibiting histamine, a

main factor of hypersensitivity diseases, including itch, pain, inflammation, fever and other syndromes, in examples of [0081] TTABLE-US-00002 for testing of histamine inhibition using 100% of each compound in each experiment. There are 1-32 examples. It is well known that insect bits are also inducing histamine release and causing itch, pain, inflammation, fever locally. In [0081] TTABLE-US-00002 phosphoric acid shows the properties of inhibiting histamine that means phosphoric acid can treat the ailments of itch, pain, inflammation and fever too.

5. Amendments in claim:

(1). Ailments are limited in the ailments caused by histamine.

(2). Forms of health care foods are elected by example in which phosphoric acid is contained.

(3). Claim listings of marking version and clean version are shown in attachments.

Yours faithfully,

Shin-Jen Shaio

Oct. 06, 2011

Attachments:

1). Amended Claim listings of marking version

2). Amended Claim listings of clean version.